

Real Life™

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Vice President Portfolio Development and Review
GWG Recommendations Translational Applications

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CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world





DISCOVERY



TRANSLATION



CLINICAL

New
Idea



Single Product
Candidate



Pre-IND or
Equivalent



Approved
Therapy

TRAN1
Therapeutic

30 months
\$4M
(Cell/Biologic)
\$2M (Drug)

TRAN2
Diagnostic

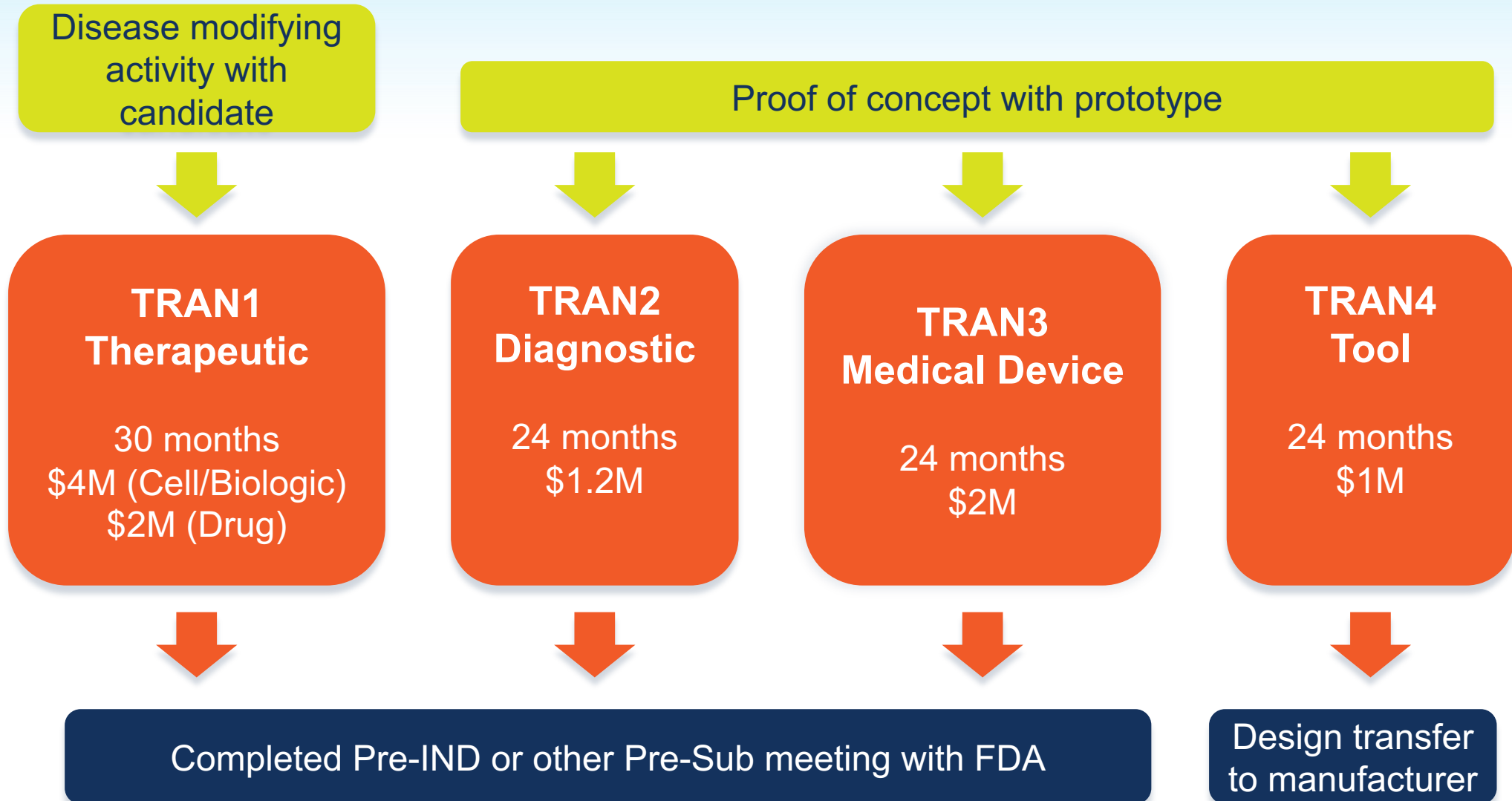
24 months
\$1.2M

TRAN3
**Medical
Device**

24 months
\$2M

TRAN4
Tool

24 months
\$1M



1. Does the project hold the necessary significance and potential for impact? (i.e., what value does it offer; is it worth doing?)
2. Is the rationale sound? (i.e., does it make sense?)
3. Is the project well planned and designed?
4. Is the project feasible? (i.e., can they do it?)
5. Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?

1 to 100 Scoring

- Score of **85 to 100**: Application has exceptional merit and warrants funding.
- Score of **1 to 84**: Application is not recommended for funding.
 - Score of **80 to 84**: Application has merit but not ready to be funded at this time. If resubmitted in a future DISCO competition, this can *bypass* positive selection and automatically undergo full scientific review.
- Applications receiving *any* score can revise and resubmit in future TRAN competitions.

CIRM TRAN Program DEI Rubric				
CRITERIA	Score of 0 to 2 Not Responsive	Score of 3 to 5 Not Fully Responsive	Score of 6 to 8 Responsive	Score of 9 to 10 Outstanding Response
1. Product Development	Inadequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	May have inadequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	Adequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	Strong discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.
	Planned/completed activities do not demonstrate an understanding of the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities are incomplete or inadequate and may not demonstrate an understanding of the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities reflect a good faith effort and have the potential to be effective in understanding the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities reflect an outstanding and comprehensive effort and are likely to be effective in understanding the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.
	Does not address limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	May not fully address limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	Addresses limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	Comprehensive discussion on limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.
2. DEI Enhancement Strategies	Has not or will not include diverse and inclusive perspectives and experience from the population that will benefit from the product, or activities proposed are not appropriate.	May not have or may not effectively or sufficiently bring diverse and inclusive perspectives and experience from the population that will benefit from the product. Activities may not match the needs of the project.	Has or will appropriately bring diverse and inclusive perspectives from the population that will benefit from the proposed product. Activities match the needs of the project.	Has or will have outstanding incorporation of diverse and inclusive perspectives from the population that will benefit from the proposed product. Activities are well matched to the needs of the project.

DEI Scores

Applications are scored for adherence to principles of DEI by all GWG Board Members with no conflict.

- **DEI Score of 9-10**
Outstanding Response
- **DEI Score of 6-8**
Responsive
- **DEI Score of 3-5**
Not Fully Responsive
- **DEI Score of 0-2**
Not Responsive

The median of all individual DEI scores determines final DEI score.

Scientific GWG
Member



Scientific evaluation (disease area expert,
regulatory, CMC, product development)

Provides scientific score on all applications

GWG Board
Member (Patient
Advocate/Nurse)



Patient perspective on significance and potential
impact, oversight on process

Provides a DEI score on all applications

Scientific
Specialist
(non-voting)



Scientific evaluation (specialized expertise as
needed)

Provides initial but not final scientific score

Positive Selection (Two-Stage) Review Process

- Performed when the total number of applications exceeds the capacity of the GWG to review in a single cycle.
- In the first stage, GWG members including patient advocates and nurse Board Members conduct a pre-review of applications and select which ones to advance to a full review.
- The CIRM President and CIRM will examine non-selected applications to determine if any merit a full review. The remainder are not considered further.
- A total of 50 applications were submitted and a total of 29 advanced to the full discussion stage by GWG.

GWG Recommendations

	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score 85-100	16	\$69,565,954	\$42,537,935
Not recommended for funding Score 1-84	11		

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

- Under Prop 14, any application that is not recommended for funding by the GWG, but which had 35% or more members score to fund the application must include a minority report.
- The minority report is included in the review summary and provides a brief synopsis of the opinion of reviewers that scored the application 85 or above.

App Number	Title	Funds Requested	Score
TRAN1-16158	Development of Cargocyte expressing IL-12 (CA-IL-12) for the treatment of metastatic cancers	\$3,196,087	84

The CIRM Team supports the majority position (Do Not Fund) for application **TRAN1-16158** and recommends that the applicants revise and resubmit for the next TRAN cycle.

Board Members with Conflicts of Interest for TRAN Applications

Maria Bonneville

Ysabel Duron

Steve Juelsgaard

Karol Watson